

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

SANDRA RALEY, §
§
Plaintiff, § CIVIL ACTION NO: 2:10-cv-00529-DF
v. §
§
WYETH LLC f/k/a WYETH, INC. §
and WYETH PHARMACEUTICALS; §
PFIZER INC., Individually and as §
Successor-in-Interest to PHARMACIA & §
UPJOHN COMPANY; and §
GALLIPOT, INC., §
§
Defendants. §

**DEFENDANT GALLIPOT, INC.'S ORIGINAL ANSWER TO
PLAINTIFF'S ORIGINAL COMPLAINT AND JURY DEMAND**

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, Defendant Gallipot, Inc. (Defendant"), and files its Original Answer to Plaintiff's Original Complaint and Jury Demand, and in support thereof shows as follows:

ANSWER

I. INTRODUCTION

1. With regard to Paragraph 1.01 of Plaintiff's Original Complaint, Defendant admits that there is a Multi District Litigation ("MDL") styled *In re Prempro* pending in the United States District Court for the Eastern District of Arkansas, Western Division. Defendant denies that Plaintiff was injured as the result of any component product distributed by this Defendant. Defendant further denies that it designed, manufactured, marketed or distributed any finished product alleged to have

caused damage to Plaintiff. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and, therefore, denies same.

II. JURISDICTION AND VENUE

2. With regard to Paragraph 2.01 of Plaintiff's Original Complaint, Defendant denies that it has committed any tort. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies same.

3. With regard to Paragraph 2.02 of Plaintiff's Original Complaint, Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies same.

4. With regard to Paragraph 2.03 of Plaintiff's Original Complaint, Defendant denies that Plaintiff has been damaged as a result of any act or omission by this Defendant. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies same.

III. PARTIES

5. With regard to Paragraph 3.01 of Plaintiff's Original Complaint, Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the residency of Plaintiff and, therefore, denies same.

6. With regard to Paragraph 3.02 of Plaintiff's Original Complaint, Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies same.

7. With regard to Paragraph 3.03 of Plaintiff's Original Complaint, Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies same.

8. With regard to Paragraph 3.04 of Plaintiff's Original Complaint, Defendant admits that it is a Minnesota corporation with its principal place of business in St. Paul, Minnesota.

IV. FACTS

A. Plaintiff Acquired Breast Cancer After Ingesting Hormone Replacement Drugs

9. With regard to Paragraph 4.01 of Plaintiff's Original Complaint, Defendant specifically denies that it manufactured the product "Bi-Pro" as alleged in Paragraph 4.01. Further, Defendant specifically denies that it is liable to Plaintiff Sandra Raley and/or that it designed, manufactured, marketed or distributed any finished product alleged to have caused injury or harm to Plaintiff. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 4.01 of Plaintiff's Original Complaint and, therefore, denies same.

B. The Creation of A Disease

10. With regard to Paragraph 4.02 of Plaintiff's Original Complaint, Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies same.

11. With regard to Paragraph 4.03 of Plaintiff's Original Complaint, Defendant specifically denies that it "joined in [any alleged] marketing and advertising scheme," continuously and vigorously promoted hormone therapy products and/or engaged in the marketing conduct as alleged in Paragraph 4.03 and subparagraphs 1-8 of Paragraph 4.03. Defendant is without knowledge or

information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 4.03 and, therefore, denies same.

12. With regard to Paragraph 4.04 of Plaintiff's Original Complaint, Defendant denies the allegations set forth in Paragraph 4.04, and specifically denies that it engaged in conduct or used "different message delivery systems" to create the alleged "disease of menopause" or "market the 'solution' of hormone replacement drugs."

13. With regard to Paragraph 4.05 of Plaintiff's Original Complaint, Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies same.

14. With regard to Paragraph 4.06 of Plaintiff's Original Complaint, Defendant denies the allegations to the extent they relate to this Defendant. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and, therefore, denies same.

15. With regard to Paragraph 4.07 of Plaintiff's Original Complaint, Defendant denies the allegations to the extent they relate to this Defendant and specifically denies that it promoted the alleged "combination hormone therapy – Premarin with Provera as a hormone therapy combination." Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 4.07 and, therefore, denies same.

16. With regard to Paragraph 4.08 of Plaintiff's Original Complaint, Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies same.

17. With regard to Paragraph 4.09 of Plaintiff's Original Complaint, Defendant denies the allegations to the extent they relate to this Defendant. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and, therefore, denies same.

18. With regard to Paragraph 4.10 of Plaintiff's Original Complaint, Defendant denies the allegations to the extent they relate to this Defendant. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and, therefore, denies same.

19. With regard to Paragraph 4.11 of Plaintiff's Original Complaint, Defendant denies the allegations to the extent they relate to this Defendant. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and, therefore, denies same.

20. With regard to Paragraph 4.12 of Plaintiff's Original Complaint, Defendant denies the allegations to the extent they relate to this Defendant. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and, therefore, denies same.

21. With regard to Paragraph 4.13 of Plaintiff's Original Complaint, Defendant denies the allegations to the extent they relate to this Defendant. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and, therefore, denies same.

V. CAUSES OF ACTION

A. Negligence

22. With regard to Paragraph 5.01 of Plaintiff's Original Complaint, Defendant specifically denies that it owed any duty to Plaintiff, that it is liable to Plaintiff, and/or that it designed, manufactured, marketed or distributed any finished product alleged to have caused Plaintiff harm or injury. Defendant denies the remaining allegations set forth in Paragraph 5.01 of Plaintiff's Original Complaint.
23. Defendant denies the allegations set forth in Paragraph 5.02 of Plaintiff's Original Complaint.
24. Defendant denies the allegations set forth in Paragraph 5.03 of Plaintiff's Original Complaint.
25. Defendant denies the allegations set forth in Paragraph 5.04 of Plaintiff's Original Complaint, including the allegations set forth in subparagraphs 1 – 5.
26. Defendant denies the allegations set forth in Paragraph 5.05 of Plaintiff's Original Complaint.

B. Negligence Per Se

27. Defendant denies the allegations set forth in Paragraph 5.06 of Plaintiff's Original Complaint.
28. Defendant denies the allegations set forth in Paragraph 5.07 of Plaintiff's Original Complaint, including the allegations set forth in subparagraphs 1 – 7.
29. Defendant denies the allegations set forth in Paragraph 5.08 of Plaintiff's Original Complaint.

C. Gross Negligence/Malice

30. Defendant denies the allegations set forth in Paragraph 5.09 of Plaintiff's Original Complaint.

D. Strict Liability

31. Defendant denies the allegations set forth in Paragraph 5.10 of Plaintiff's Original Complaint.
32. Defendant denies the allegations set forth in Paragraph 5.11 of Plaintiff's Original Complaint.

33. Defendant denies the allegations set forth in Paragraph 5.12 of Plaintiff's Original Complaint.
34. Defendant denies the allegations set forth in Paragraph 5.13 of Plaintiff's Original Complaint.
35. Defendant denies the allegations set forth in Paragraph 5.14 of Plaintiff's Original Complaint.
36. Defendant denies the allegations set forth in Paragraph 5.15 of Plaintiff's Original Complaint.

E. Misrepresentation and Fraud

37. Defendant denies the allegations set forth in Paragraph 5.16 of Plaintiff's Original Complaint.
38. Defendant denies the allegations set forth in Paragraph 5.17 of Plaintiff's Original Complaint.
39. Defendant denies the allegations set forth in Paragraph 5.18 of Plaintiff's Original Complaint, and specifically denies that Plaintiff is entitled to recover any alleged actual, compensatory or exemplary damages from this Defendant.

40. Defendant denies the allegations set forth in Paragraph 5.19 of Plaintiff's Original Complaint.

F. Breach of Warranties

41. Defendant denies the allegations set forth in Paragraph 5.20 of Plaintiff's Original Complaint.
42. Defendant denies the allegations set forth in Paragraph 5.21 of Plaintiff's Original Complaint.

VI. DAMAGES

43. Defendant denies the allegations set forth in Paragraph 6.01 of Plaintiff's Original Complaint, and specifically denies that it is liable to Plaintiff for any alleged damages, including but not limited to any alleged actual, compensatory or exemplary damages. Defendant further denies that it is liable to Plaintiff for any alleged attorneys' fees, expenses, costs, prejudgment interest or post-judgment interest.

Prayer for Relief

44. Defendant denies the allegations set forth in the Prayer for Relief in Plaintiff's Original Complaint, and specifically denies that Plaintiff is entitled to recover from this Defendant any alleged actual, compensatory or exemplary damages, attorneys' fees, expenses, costs, prejudgment interest or post-judgment interest.

GENERAL DENIAL

45. Pursuant to FED. R. Civ. P. 8(b), Defendant generally denies all material allegations of Plaintiff's Original Complaint, save and except for those items specifically admitted in the preceding paragraphs of this Answer.

AFFIRMATIVE DEFENSES

46. Pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, the Complaint fails to state a claim against this Defendant upon which relief can be granted.

47. Pursuant to Rule 9(b) of the Federal Rules of Civil Procedure, the Complaint fails to state with particularity the circumstances and facts constituting any misrepresentation or fraud.

48. Pleading further, should same be necessary, Defendant denies that it designed, manufactured, marketed or distributed any finished product alleged to have caused damage to Plaintiff.

49. Pleading further, should same be necessary, in the absence of proof by Plaintiff that any finished product or products at issue was made, distributed or marketed by this Defendant, Defendant is not liable for any alleged claims or damages asserted by Plaintiff.

50. Pleading further, should same be necessary, Plaintiff's claims against this Defendant are preempted by federal law.

51. Pleading further, if necessary, Plaintiff's claims against this Defendant are barred by the learned intermediary doctrine.

52. Pleading further, if necessary, Plaintiff's claims against this Defendant are barred by the sophisticated user, component parts, raw materials supplier or bulk sales doctrines.

53. Pleading further, if necessary, to the extent that Plaintiff's claims are based upon a theory providing for liability without proof of causation, said claims violate Defendant's due process rights under the United States Constitution and the Texas Constitution.

54. Pleading further, if necessary, Defendant pleads the affirmative defense of Comment k to Section 402a of the Restatement (Second) of Torts (1965).

55. Pleading further, if necessary, Plaintiff's claims against Defendant are subject to the limitations and requirements of Sections 4 and 6 of the Restatement (Third) of Torts: Products Liability.

56. Pleading further, if necessary, at all relevant times, proper warnings, information, and instructions were provided or made available for any alleged component product of Defendant, pursuant to generally recognized prevailing standards in existence at the time. Any alleged component product distributed by Defendant at issue in this litigation was not defective.

57. Pleading further, if necessary, at all times relevant, any component product distributed by Defendant was in accordance with applicable state-of-the-art and state-of-the-scientific knowledge and in accordance with and pursuant to all applicable statutes and regulations, including those of the United States Food and Drug Administration.

58. Pleading further, if necessary, this Defendant affirmatively asserts and pleads that Plaintiff's injuries and damages, if any, were the result of pre-existing and/or subsequent conditions which were

unforeseeable by this Defendant and which were unrelated to any conduct of this Defendant or any component product allegedly placed in the stream of commerce by this Defendant.

59. Pleading further, if necessary, Plaintiff's claims are barred in whole or in part by assumption of the risk and/or informed consent. Plaintiff had full knowledge of, accepted and assumed any and all risks and possible adverse effects related to the use of any product.

60. Pleading further, if necessary, the injuries and/or damages alleged by Plaintiff, if any, may have been caused, in whole or in part, by operation of nature or act of God.

61. Pleading further, if necessary, this Defendant affirmatively asserts and pleads that Plaintiff's injuries and damages, if any, were the result of a new and independent, intervening and/or superseding cause unrelated to any conduct of this Defendant or any component product allegedly placed in the stream of commerce by this Defendant.

62. Pleading further, if necessary, if Plaintiff should settle with any other person or party, then Defendant reserves its rights under Chapters 32 and 33 of the Texas Civil Practice and Remedies Code regarding an election of credit and reduction in the amount of damages to be recovered by the Plaintiff.

63. Pleading further, if necessary, Defendant denies any and all alleged liability on its part with regard to the claims raised by Plaintiff in this litigation. In the unlikely event, however, that the Court or any fact finder ultimately finds any liability against this Defendant and other Defendant or Defendants, then this Defendant avails itself of the rights of contribution and indemnity against said other Defendant(s) pursuant to Chapter 33 of the TEX. CIV. PRAC. & REM. CODE and any other applicable statute or common law rule.

64. Pleading further, should same be necessary, Plaintiff's claims are barred in whole or in part by the doctrine of laches.

65. Pleading further, should same be necessary, Plaintiff's claims are barred in whole or in part by the applicable statute of limitations, statute of repose and/or Section 16.012 of the Texas Civil Practice & Remedies Code.

66. Plaintiff's claims are barred by Section 82.003 of the Texas Civil Practice & Remedies Code.

67. Plaintiff's claims are barred by Section 82.007 of the Texas Civil Practice & Remedies Code.

68. Pleading further, if necessary, Defendant denies that any act or omission by this Defendant was malicious, willful, wanton, reckless or grossly negligent and therefore, Plaintiff's claims for punitive or exemplary damages are barred.

69. Pleading further, if necessary, Defendant specifically pleads and incorporates by reference all applicable caps and limitations upon any award of damages, including any actual, compensatory or exemplary damages, which are provided by law. Defendant further pleads that its liability, if any, which is denied, be limited by the provisions of § 41.001 *et seq.*, TEX. CIV. PRAC. & REM. CODE and any other applicable statute or common law rule, which are pled and incorporated herein by reference.

70. Pleading further, if necessary, Plaintiff's claims for exemplary damages against Defendant cannot be sustained because an award of exemplary damages under Texas law by a jury that (1) is not provided constitutionally adequate standards of sufficient clarity for determining in the appropriate imposition of, and the appropriate size of, an exemplary damages award, (2) is not adequately instructed on the limits of exemplary damages imposed by the applicable beliefs of deterrents and punishment, (3) is not expressly prohibited from awarding exemplary damages, or

determining the amount of an award of exemplary damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including without limitations, the residence, wealth, and corporate status of Defendant, (4) is permitted to award exemplary damages under a standard for determining liability for exemplary damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes exemplary damages permissible, (5) is not properly instructed regarding Plaintiff's burden of proof with respect to each and every element of a claim for exemplary damages, and/or (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would be arbitrary and excessive and would violate Defendant's due process and equal protection rights guaranteed by the 5th and 14th Amendments to the United States Constitution and Article I, §§ 3 and 19 of the Texas Constitution, and would be improper under the common law and public policies of the State of Texas.

71. Pleading further, if necessary, Plaintiff's claims for exemplary damages against Defendant cannot be sustained because an award of exemplary damages in this case would constitute impermissible multiple punishments for the same wrong and the standards for determining liability for and the amount of exemplary damages to be assessed is void for vagueness and would be in violation of Defendant's due process and equal protection rights guaranteed by the 5th and 14th Amendments to the United States Constitution. Defendant further pleads that Plaintiff's claim for exemplary damages violates the 4th, 5th, 6th, 7th, 8th, and 14th Amendments of the United States Constitution and sections 3, 9, 13, and 19 of Article I of the Texas Constitution.

72. Pleading further, if necessary, Defendant asserts that Plaintiff is not entitled to recover exemplary damages jointly and severally.

73. Pleading further, if necessary, Defendant asserts the limitations for pre-judgment interest set forth in the Texas Finance Code.

74. Pleading further, if necessary, Defendant hereby gives notice that it intends to rely upon any other defense that may become available or appear during any discovery proceedings in this cause and hereby reserves its rights to amend its answer to assert any such defense.

75. Defendant incorporates by reference, to the extent applicable to this Defendant, any affirmative defenses raised by the other Defendants herein.

DEFENDANT'S JURY DEMAND

76. Pursuant to FED. R. CIV. P. 38, Defendant requests a jury trial.

WHEREFORE, PREMISES CONSIDERED, Defendant Gallipot, Inc. respectfully prays that this Court reject and deny all of Plaintiff's claims against this Defendant, that upon final hearing Plaintiff take nothing from this Defendant, that Defendant recover its costs and fees in connection with this case, and that Defendant be awarded such other and further relief, both at law and in equity, to which this Defendant may show itself to be justly entitled.

Respectfully submitted,

By: /s/ David M. Macdonald

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ATTORNEYS FOR DEFENDANT
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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document has been forwarded to the following counsel of record via Electronic Filing, Certified Mail, Return Receipt Requested, or First Class United States Mail, as set forth below on this 18th day of January, 2011:

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